IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA

Alexandria Division

UNITED STATES OF AMERICA v. SB MEDICAL, INC., and HANOCH DAVID STEIN, Defendants.	Criminal No. 1:14-CR-397 Honorable Anthony J. Trenga Trial Date: May 13, 2015

GOVERNMENT'S RULE 16(a)(1)(G) NOTICE

Pursuant to Rule 16(a)(1)(G) of the Federal Rules of Criminal Procedure and Rules 702, 703, and 705 of the Federal Rules of Evidence, the United States hereby notices its intent to use expert testimony. The United States may call the expert witnesses identified below. The statement of expert qualifications of each witness is attached hereto. Those qualifications, along with review and analysis of relevant reports, facts, and evidence, set forth the bases for their opinions.

1. Dr. Charles E. Lee

The United States may call Dr. Charles E. Lee as an expert in the FDA's approval process for prescription drugs and compliance requirements for all prescription drugs distributed in the United States. Dr. Lee is employed as a senior medical advisor in the Office of Unapproved Drugs and Labeling Compliance in the Office of Compliance at the FDA Center for Drug Evaluation and Research. His curriculum vitae is attached hereto as Exhibit 1.

The United States anticipates that Dr. Lee will testify about FDA requirements for the marketing of medical drugs in the United States, including premarket approval of new drugs and compliance with labeling requirements. Dr. Lee is also expected to describe the uses,

restrictions, and potential side-effects of each drug referenced in the indictment. In addition, Dr. Lee has reviewed samples of the following drugs that were obtained from Defendants: Aclasta, Actemra, Botox, Dysport, Lucentis, Orencia, Prolia, and Remicade. Dr. Lee is expected to testify that each of these drugs is misbranded, either because the drug was not approved for distribution in the United States, or because the drug did not bear the FDA-approved labeling on its package or product container and did not contain the FDA-approved package insert.

The bases of Dr. Lee's opinions include his experience and training at the FDA, personal review of the packaging of the above-described prescription drug, and/or personal review of the FDA-approved packaging for those drugs.

2. Marjorie Shulman

The United States may call Marjorie Shulman as an expert in the FDA's regulation and approval process for medical devices marketed in the United States, including the classification of such devices and the FDA Premarket Approval ("PMA") process. Ms. Shulman is employed as a Supervisor Consumer Safety Officer and the Director of the Premarket Notification Section in the Office of Device Evaluation within the FDA Center for Devices and Radiological Health. Ms. Shulman's curriculum vitae is attached hereto as Exhibit 2.

The United States anticipates that Ms. Shulman will testify about FDA requirements for the marketing of medical devices in the United States, including premarket approval of new devices and compliance with labeling requirements. Ms. Shulman is also expected to describe the uses, restrictions, and potential side-effects of each device referenced in the indictment. In addition, Ms. Shulman has reviewed the following devices that were obtained from Defendants: Artz, Euflexxa, Hyalgan, Juvederm, Orthovisc, Radiesse, Restylane, and Synvisc. Ms. Shulman is expected to testify that each of these devices is misbranded, either because the device was not

approved for distribution in the United States, or because the device did not bear the FDA-approved labeling on its package or product container and did not contain the FDA-approved package insert.

The bases of Ms. Shulman's opinions include her experience and training at the FDA, personal knowledge and familiarity with the PMA process, personal review of the packaging of the above-described medical devices, and/or personal review of the FDA-approved packaging for the products in the United States.

3. Douglas Albright, Ranee Easter, Angie Mohrhaus, Nohora Shockey, and Tim Yi

The United States may call Douglas Albright Ranee Easter, Angie Mohrhaus, Nohora Shockey, and Tim Yi as experts in forensic chemistry. These experts are all employed as chemists in the FDA's Forensic Chemistry Center. Their curricula vitae are attached hereto as Exhibits 3-7.

The United States anticipates that these experts will testify that they analyzed the packaging and content of two cartons, recovered from David Stein's residence on Menlo Road in Baltimore, Maryland, that purported to be the drug Botox. They are expected to testify that neither the labeling nor the contents of those cartons were consistent with authentic Botox.

The bases of these opinions include analytical tests performed on the substance contained in the cartons and a visual analysis of the cartons' labeling as compared with a sample of authentic Botox provided by the manufacturer. These opinions are also based on the experts' education, experience, and training in the field of forensic chemistry, as summarized in their curricula vitae. The experts' written report related to these findings was provided to defense counsel on April 29, 2015.

4. Scott Rubin

The United States may call Special Agent ("SA") Scott Rubin as a witness. SA Rubin is employed as a computer forensic examiner in the FDA Office of Criminal Investigations. SA Rubin is expected to provide testimony relating to the forensic examination of computer and smart phone equipment that he conducted in connection with the investigation into SB Medical, Inc., David Stein, and others. SA Rubin's curriculum vitae is attached hereto as Exhibit 8.

SA Rubin's testimony will involve his technical and specialized knowledge regarding the forensic examination of computer equipment. SA Rubin is expected to testify concerning the forensic images he made of particular computer and smart phone equipment. SA Rubin will describe the process and purpose of making a forensic image of the equipment, the methods and/or software used in the examination, and the results of the examination. As such, the Government views SA Rubin as a fact witness. Nonetheless, the Government notices Rubin as an expert in computer and cellular phone forensics out of an abundance of caution.

The United States intends to seek a stipulation as to SA Rubin's testimony, as there have been no issues expressed to date regarding the forensic examinations he conducted. SA Rubin may be called in the event such a stipulation is not obtained.

The items SA Rubin imaged include the following:

a. One Samsung Galaxy S3 Smart Phone seized from David Stein's residence on Menlo Road in Baltimore, Maryland;

b. One ASUS laptop computer, containing a back-up of an iPhone associated with a phone number ending in 1300, seized from David Burke; and

c. One HTC1 Smart Phone seized from David Burke.

Date: April 29, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 29, 2015, I electronically filed the foregoing with the Clerk of Court using the CM/ECF, which will then send a notification of such filing (NEF) to the counsel of record for the defendants.

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